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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/142,557	09/11/1998	LINDA MAY PILARSKI	P-1459(O)	2357

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EXAMINER

FONDA, KATHLEEN KAHLER

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/142,557

Applicant(s)

PILARSKI, LINDA MAY

Examiner

Kathleen Kahler Fonda, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 171-197, 201 and 203-206 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 171-197, 201 and 203-206 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 171-197, 201, 203, and 204 are again rejected, and new claims 205 and 206 are now rejected, under 35 U.S.C. 103(a) as being unpatentable over HAMANN et al. (K) in view of FALK et al. (A), for the reasons set forth in the Office action of 11-19-02.

Applicant's arguments filed 05-22-03 have been fully considered but they are not persuasive. Applicant argues in the second paragraph on page 9 of the response of 05-22-03 that if the references applied do not "teach" the claimed invention, questions such as motivation and reasonable expectation of success are moot. The Examiner does not agree. The invention need not be taught by the references. Under § 103, a reasonable suggestion of the claimed invention to one of ordinary skill in the art based on properly combined references, and a reasonable expectation of success, are sufficient. The Examiner continues to maintain, for reasons of record, that the steps of the claimed methods are reasonably suggested by the prior art as applied. Furthermore, Applicant admits at the bottom of page 9 of the response of 05-02-03 that "Hamann discloses that HA causes a concentration-related increase in proliferation of

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CD34+ eosinophil progenitor cells." Then Applicant continues to state that "Applicant is unable to find 'the teaching of augmentation of blood cell production taught by Hamann.'" These two statements do not appear to be consistent to the Examiner, because eosinophils are blood cells. Applicant argues that there would have been no reasonable expectation of success, but fails to provide any reasons indicating why this should be so. HAMANN teaches that hyaluronic acid as claimed has the necessary activity *in vitro*, and FALK discloses that hyaluronic acid is suitable for administration to patients. Absent evidence to the contrary, it is reasonable to expect that hyaluronic acid would maintain its activity *in vivo*.

Although Applicant does not address it in the response of 05-22-03, the Examiner notes that claims 171-197, 201, 203, and 204 now require that "the hyaluronic acid is not topically administered in combination with a non-steroidal anti-inflammatory drug (NSAID)." HAMANN, which is the reference relied upon for the teaching of the pharmaceutical activity underlying the claimed methods, does not teach or suggest topical administration of hyaluronic acid together with an NSAID. Thus, the claims remain obvious despite Applicant's amendment.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile

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transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

INTERNET INFORMATION: Secure and confidential access to patent application status information is now available; see <http://www.uspto.gov/ebc/index.html> for more information. Also, <http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm> may be used to pay patent maintenance fees, pay non-filing application fees, and maintain USPTO deposit accounts.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kathleen Kahler Fonda, at telephone number (703) 308-1620. Examiner Fonda can generally be reached Monday through Friday from 7:30 a.m. until 4:00 p.m. If the Examiner cannot be reached, questions may be addressed to Supervisory Patent Examiner James O. Wilson at (703) 308-4624. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.



Kathleen Kahler Fonda, Ph.D., J.D.
Primary Examiner
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